EXHIBIT 520

Discussion DRAFT – Not for External Distribution

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Draft date 02-06-08

DISCUSSION DRAFT v.8 – Post 1/31/08

HDMA BEST PRACTICES FOR CONTROLLED SUBSTANCES (CS) SUSPICIOUS ORDERS AND DIVERSION PREVENTION

Introduction

These *Business Practices for Controlled Substances and Diversion Prevention* have been developed as part of the pharmaceutical distribution industry's commitment to the safe and efficient distribution of drug and pharmaceutical products to the patients who need them. They are consistent with, and further amplify, the distributors' outstanding track record of supporting and implementing initiatives designed to improve the safety, security and integrity of the drug supply. They have been prepared in recognition of the growing problem of misuse of Controlled Substances and of the key role distributors play within the prescription drug supply chain.

While drug wholesale distributors, like all nongovernmental entities, do not have the investigative powers and resources to guarantee that certain products will not reach illicit or illegal markets, they are uniquely situated to perform due diligence in order to help support the security of the controlled substances distribution system. Even with due diligence, it is not always possible to determine the specific final selling point, or patient use, of controlled substances.

However, rigorous due diligence can aid in providing a greater level of assurance that those who purchase controlled substances from wholesale distributors, intend them to be used for legitimate - and legally acceptable - patient needs. In other words, with such due diligence, it is possible to reduce the probability that controlled substances will reach locations within the supply chain for which they are not intended.

The best practices defined below have been designed to identify facts and information surrounding a controlled substance product order that will aid in determining whether the product will be used for legitimate dispensing purposes.

History

In 1970, Congress enacted into law the Controlled Substances Act (CSA) as part of Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. The CSA provides the Drug Enforcement Administration (DEA) within the Department of Justice (DOJ) with the legal authority to regulate the manufacture, importation, possession and distribution of certain drugs. An additional federal agency, the Department of Health and Human Service's Food and Drug Administration (FDA), maintains additional regulatory authority over many other aspects of the drug supply chain safety and security. The CSA also created a closed system of distribution for those authorized to handle controlled substances. Since its enactment in 1970, the CSA has been amended several times, including:

The Psychotropic Substances Act of 1978
The Controlled Substances Penalties Amendments Act of 1984
The Chemical Diversion and Trafficking Act of 1988
The Domestic Chemical Diversion and Control Act of 1993
The Federal Analog Act
The Methamphetamine Precursor Control Act which was superseded by the Combat Methamphetamine Epidemic Act of 2005

The regulations outlined in Title 21, United States Code part 1300 to end contain the rules and regulations for all individuals and firms desiring to conduct business in controlled substances. All individuals and firms must be registered with the DEA and are required to maintain complete and accurate inventories and records of all transactions involving controlled substances as well as security for the storage of controlled substances.

One major requirement under the above entitled code places a duty upon distributors to report suspicious orders of controlled substances. Specifically, Title 21, United States Code section 1301.74 (b) states that

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Distribution Industry Commitment to Securing the Supply of Controlled Substances

While distributors have always recognized and followed requirements that registrants identify and report "suspicious orders" of controlled substances and listed chemicals, recent concerns about the potential misuse of controlled substances has elevated their awareness, and that of the DEA, and the public, to the need for greater rigor in evaluating the purchase orders for such products. For example, in three public statements to Congressional Committees[1] DEA has noted the growing problem of diversion and abuse of controlled pharmaceuticals and has indicated they are taking stronger measures to address them.

Based on the expertise and strong endorsement of our members, the Healthcare Distribution Management Association (HDMA) has developed the following recommendations for meeting and exceeding DEA's expectations. We are confident that implementation of these guidelines will

[1] See Testimony provided by Deputy Administrator Joseph T. Rannazzisi, December 13, 2005, July 26, 2006 and September 18, 2007.

aid in the appropriate distribution of controlled substances to supply chain partners involved in the legitimate dispensing of these important products to the patients they serve.

I. KNOW YOUR CUSTOMER

Before opening up a new customer account, it is recommended that the distributor obtain background information on the customer and their business, review the information for discrepancies, and, where appropriate, verify the information. Distributors may tailor this part of their best practices to the type of customer under review. Should they do so, it is recommended that they categorize customers according to the customer's DEA license type: 1) Physician, 2) Retail, 3) Distributor. The following is recommended:

a. Information gathering

All information should be completed by the owner, pharmacist in charge, or equivalent designee for non-pharmacy customers. All documents providing requested information should be signed by the owner, pharmacist in charge or equivalent designee. It is recommended that the potential customer have the signature notarized or that they sign the questionnaire with the statement: "*I declare under penalty of perjury that the foregoing is true and correct. Executed on [date].*" The Information gathering step would include:

- Provide potential customer with a credit application
- Provide potential customer with a background questionnaire requesting the following information:
  - Business background
  - Customer base
  - Average number of scripts filled each day
  - Average number of CS item scripts filled each day
  - Percent of CD purchases compared to overall purchases
  - Provide potential customer with the questions recommended by DEA
  - Request copies of all their state and federal licenses
  - Certification they are not conducting Internet business and will notify the distributor before conducting any Internet business
  - If they are conducting internet business obtain the following information:
    - How long have they been conducting Internet business
    - Products they wish to purchase
    - Quantities of those products they wish to purchase
    - Doctors who will be writing scripts including DEA & State license numbers, address, telephone numbers, etc.
    - NABP VIPPS check
  - Names of individuals authorized to sign DEA Forms 222
  - Dates of the most recent DEA audit. And a description of the outcome.

Identification of physicians, pain management clinics, or other treatment centers that are the potential customers' most frequent prescribers or highest purchasing doctors.
It is also recommended that the distributor update the questionnaire(s) periodically, especially if concerns arise during prior investigations.

b. Information Review

After the information is received from the customer, a thorough review is recommended. The review would include:

Verify credit application is complete and carefully review the information submitted
Verify customer background information supplied is complete and carefully review the information contained
Verify answers to questions recommended by DEA are complete and carefully review the information contained
Verify the CS schedule their state and federal licenses authorized them to handle

c. Independent Investigation

It is also recommended that the distributor independently investigate the potential customer by seeking the following information about them:

Verify DEA license is current and valid
Verify state license is current and valid
Check with the prospective customer's local DEA office for any information regarding the potential customer such as DEA actions against them
Check with state oversight authorities including state Boards of Pharmacy (potential pharmacy customers) and Boards of Medicine (for potential physician customers) to request further background information, such as state actions against them (some states may provide readily accessible information through the state's Web site.)

Check the DEA Web site and the Federal Register for any actions against the potential customer
Complete Goggle search, for example, to determine if any potential Internet business can be identified

Additional Recommendations and Documentation

It is recommended that

- Individuals selected to develop questionnaires for part (a) and conduct reviews and investigations under parts (b) and (c) above receive appropriate training.

- Document all results and retain documentation records.
- Site inspections are not required but are suggested if the distributor believes that further information about the customer is warranted.
- After completing the Information Review and Independent Investigation, the reviewer should sign and date the information to indicate that they have conducted a thorough/complete review, and that the information contained is accurate and complete to the best of his/her knowledge.
- The distributor may wish to conduct periodic updates and review the information that the customer initially provides to the distributor.
- The distributor may also maintain an internal list of registrants as a "do not ship list". For example, if the distributor has received reliable information that a pharmacy knowingly sold controlled substances to illicit Internet pharmacies. *[Reviewers: Should we be this explicit about this point.]*

II. SUSPICIOUS ORDER MONITORING

a. System Design

It is recommended that the distributor develop an electronic system, and accompanying SOPs, to meet the DEA's expectations to "design and operate a system to disclose to the registrant suspicious orders of controlled substances". Distributors are encouraged to identify responsibilities for identifying, investigating and reporting potentially suspicious orders based on the decision chart included as Attachment 1 of these Best Practices. Specific elements of the monitoring system are further described below.

b. Identify Product and Customer Characteristics

Separate/classify/group your customers into appropriate/different class of trades. For example, retail pharmacies, hospitals, doctors, dentists, etc.

Separate the controlled substances the distributor sells into groups or "families" of drugs. For example, all CS items containing Codeine, all CS items containing Cocaine.

Distributors may use the National Technical Information Service (NTIS) system which identifies each particular CS SKU by NDC number and lists the active ingredient. The term DEA base code or drug code is setup by NDC number. An electronic copy of this information may be used to set averages.

Alternatively, the distributor may choose to identify each family of drugs and track the unit dose (tablet) of each SKU.[2]

[2] It should be noted that this method is difficult because of the different strengths of the drugs.

c. Develop "Thresholds" to Identify Order of Interest
"Thresholds" for identification purposes may be made by using averages dispensed by the facility consistent with the class of customer.

Calculate the average single order and the average monthly order per "family," per customer, and class of trade. A minimum of six months sales history or a maximum of 24 months sales history is recommended.

Also, identify orders of "unusual" size. It is recommended that distributors follow past DEA criteria. Specifically, DEA has recognized three times the average C-II and reportable C-III orders as meeting the unusual threshold. In the past the DEA has recognized eight times the other C-III-V orders as meeting the unusual threshold.

Unusual (based on frequency and deviating substantially from a normal pattern) must also be identified to meet DEA requirements.

d. Stop Shipments of an Order of Interest

Option 1 – Stop shipments of the individual drug code product that is an Order of Interest
Neither the individual orders of that specific drug code product order, nor any portion of that entire specific drug code product order that meets or exceeds the thresholds identified above should be shipped. It is recommended that the electronic system contain a process to automatically "block" the order or otherwise stop the product from being shipped. They may, however, ship any non-Controlled Substances included with the order or other controlled substances products that did not exceed a threshold as defined in their monitoring system. Distributors may choose to report immediately or may investigate the order as described in III below.

Option 2 – Distributors may ship a portion of the entire individual drug code product that is an Order of Interest
Distributors may determine that, based on the anticipated customer's needs, it would be necessary for them to ship part of the order of the individual drug code product that triggered the thresholds. They may also ship any non-Controlled Substances included with the order or other controlled substances products that did not exceed a threshold as defined in their monitoring system. If they decide to ship part of the drug code product in the order of interest, they should immediately proceed to investigate the order as described in Section III below.

III. INVESTIGATION OF ORDERS OF INTEREST; SHIPMENT DECISIONS

Should a distributor wish to reconsider and ship an order (or part of such an order) that meets the threshold and is thereby identified as an "order of interest", it is recommended that he or she first conduct an investigation of the order to determine whether the order should be reported or if it may be shipped.

a. Designating an Investigator

It is recommended that the distributor designate a person with suitable experience and background to investigate potential suspicious orders. Such criteria as length of service, education/training, and expertise may be factored into the choice of the individual.

b. Elements of the Investigation

If it is determined that the order should be investigated further, it is recommended that the investigation include three elements as described below. Site inspections are not required, but are suggested if the investigation provides insufficient verification of the order.

Review prior orders

The distributor should review past purchases by the same customer for trends/discrepancies to determine if:

- The distributor had to investigate a prior order ? What was the circumstance of that investigation? Was this order the same, or how did it differ?
- There had been an increase (or decrease) in orders for this "group" or "family" of products?
- There had been other unusual activity such as "spikes" in their orders?
- There had been a decrease in orders for other products (potentially indicating a shift in focus of customer base.)
- There been a change in the customer's operating environment (such as a new pain clinic has recently opened in the pharmacy's neighborhood)?
- There had been a change in availability of drugs for pain management (such as a new drug dosage form that has recently been approved by FDA)?
- Whether there are end of year C-II quota issues?

Interview customer

Ask: Why is there an "unusual" order? What will customer do with it? Who is prescribing it? (Who, what, when, where, why, how?)

Verify customer input – (where appropriate)

How and what information is to be verified will be determined on a case by case basis, but examples of information that could be verified include:

- If a customer says there is a new pain clinic located nearby, verify clinic's existence, name, address
- If the customer says they called DEA, verify that they actually did so

If the customer states that a natural disaster destroyed their pharmacy and they must restock, verify disaster
If they claim they "lost" a shipment, verify loss

c. Documentation

All investigations should be documented and records retained in an appropriate location within the firm (such as with the customer's records).

At a minimum, documentation should include the name(s), titles(s) and other relevant identification of the purchaser contacted (e.g., "pharmacist in charge"), dates of contact, and a full description of information provided by the purchaser. A description of the final conclusion of the investigation, including why it was (or was not) deemed "Suspicious" by the reviewer, is recommended. Copies of any written information provided by the purchaser should also be retained.

d. Shipment Decisions and SOPs

- Decisions to ship an "order of interest" should be made by a person specifically authorized to conduct an investigation and release the order.
- Distributors are encouraged to develop an SOP describing how the investigation would be conducted. The SOP should give guidance to the staff conducting the investigation that is reflective of the distributors' and customers' business conditions but allows the flexibility to adjust the investigation to tailor it to the individual circumstances that are likely to occur.

e. Shipment and Reporting (under 1301.74(b)) Decision Options

At the completion of the investigation, the distributor decides how to resolve the order. The distributor may find that the order is "Suspicious" if:

- Neither the customer nor the verification steps provided sufficient information to make an informed judgment that the order would likely be distributed/dispensed or otherwise used for purposes that were consistent with the customers' usual course of business.
- Information obtained during the investigation provided reason to believe the product may be used for illegal or illicit purposes, instead of being dispensed consistent with the customers' usual course of business.

***[Reviewers** – is the above adequate? Do we need to further define the point when the order becomes suspicious? What information did you receive that told you it was suspicious? What information did you receive that told you it was NOT suspicious and you could ship? What*

happens if you determined the order was not suspicious – shipped it - and you receive the same order the next day? Do you conduct another investigation? Do you just ship?]

The following shipment and reporting decisions (under 1301.74(b)) are possible.

1. Ship orders that do not meet/exceed thresholds – do not report to DEA
2. Cancel order – Order is "Suspicious" - report to DEA
3. Cancel/withdraw the order – customer mistake or other error- do not report to DEA
4. Investigate order, cancel - Order is "Suspicious" - report to DEA
5. Investigate, no concern identified, ship — Do not report to DEA
6. Ship part of the order, investigate, – Order is "Suspicious" - report to DEA (this 6th decision point is only applicable if Option 2 above is accepted.)

Shipment and Reporting Decision Matrix			
	Cancel order, report to DEA	Cancel or withdraw order, do not report to DEA	Ship product, do not report to DEA
1. Order does not meet/exceed thresholds			✓
2. Order is identified as "Suspicious" (without further investigation)	✓		
3. Investigate - order is error/mistake		✓	
4. Investigate – order is "suspicious"	✓		
5. Investigate – order is justified			✓
6. Partial shipment, investigate, order is "suspicious"	✓		

IV. FILE SUSPCIOUS ORDER REPORTS WITH DEA

a. Immediate DEA Notification

Orders with readily identifiable "suspicious" characteristics must be reported to DEA upon identification.

Once the distributor has made the determination the order is suspicious, a phone call to report the order to the local DEA office is recommended to meet the requirement to notify "when discovered" (unless DEA provides other direction). Provide additional documentation to DEA upon request.

b. Correspondence for Reporting

It is recommended that all written correspondence with the DEA (containing Suspicious Order reports) should be sent registered mail with a return receipt requested, by electronic mail, or by other system to demonstrate that the DEA has received the notification. Although written correspondence to the local DEA office is encouraged as a follow-up to a phone notification, distributors are encouraged to discuss whether the local DEA office wishes to receive a follow-up written notice and the form for such written communications.

The cover letter for submittals of suspicious order reporting may read: "This report is submitted to you in accordance with the requirements outlined in 21 CFR 1301.74(b) and is for (*company name*) and the month of ( )." When the return receipt is received back it should be stapled to the cover letter as proof of submittal. *(You may want to title the report 21 CFR 1301.74(b) report.)*

In some states, additional reporting requirements may apply. Distributors should determine if a state report is required and comply accordingly.

It is recommended that the same person conducting the investigation, or deciding to cancel the order, also provide the report to DEA (.

c. Documentation
All additional contact with the DEA, either by telephone or in-person, should be documented and a record of the contact maintained.

V. EMPLOYEES/TRAINING AND STANDARD OPERATING PROCEDURES (SOP)s

a. Employees/Training
Individuals working in CS areas should be screened and selected for their attention to detail, ability to recognize the importance of accuracy, length of tenure with the company, and work ethic.

It is recommended that employee training:
- Include a review of DEA rules and regulations
- Fully cover the firm's procedures for compliance
- Include backup training to cover instances when the primary associate responsible for suspicious order monitoring will not be available (e.g., due to vacation leave, sick leave, etc.)
- Provide for periodic retraining.

It is appropriate to train all personnel involved in:
- Receiving, shipping, handling and record keeping of CS items.
- Sales staff who "bring in" new accounts and interact with customers,
- Associates who review, investigate and/or release an order. .

Document all training of personnel regarding the storage, handling and record keeping of CS information and business practices.

b. SOPs

It is recommended that specific written company SOPs be developed and maintained based on these guidelines.

VI. ADDITIONAL RECOMMENDATIONS

It is recommended that the distributor include the following additional steps to maintain the suspicious orders system within their firm:

Conduct periodic internal audits of suspicious orders, compliance procedures and results.

- Periodically review and revise internal SOPs for compliance with 1301.74(b) and revise employee training requirements/procedures.

- Periodically review their monitoring system, including the system design and the thresholds, to determine if revisions should be developed. For example, if the FDA approves a new controlled substance, or a new indication for use of an existing controlled substance, revisions to the thresholds may be needed.

Glossary of Abbreviations *[note to reviewers: this Glossary is currently incomplete, but will be revised after RAC review on 2-7-08]*

	Abbreviation	**Term_____**
	CS	Controlled Substance as defined by DEA in (*give regulation site*)
	NABP	National Association of Boards of Pharmacy
	VIPPS	Verified Internet
	SKU	Stock Keeping Unit
	CSA	Controlled Substances Act
	DEA	Drug Enforcement Administration
	FDA	Food and Drug Administration
	C-I, C-II, C-III, C-IV, C-V	References the DEA's designation of individual controlled substances into one of the five levels under 21 CFR _____(*Provide site*)